

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/522,634
Filing Date : January 25, 2005
First Named Inventor : David Michael Hill
Attorney Docket No. : AAT-15784
Confirmation No. : 7390
Title : FINISHING POWDERS

Examiner : Michael C. Miggins
Art Unit : 1794

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Declaration is being submitted in support of Amendment "E" in the above-referenced matter, which has been submitted in connection with a Request for Continued Examination.

I, Dr Adrian Łyszkowski, hereby declare as follows:

1. I have a degree from the University of St. Andrews, Scotland, UK in the field of chemistry. I am presently employed by SSL International PLC and have worked in the rubber goods, particularly condom industry for 14 years.
2. In the Advisory Action mailed in this matter on October 28, 2008, the Examiner made reference to Brindle, U.S. Pat. 5,405,666, which discloses that slip properties can be achieved by dispersing substantially spherical micro-particles into a binder to form a thin film coating on the skin-contacting surface of an article such as a glove or a condom, and then applying a surfactant or long chain fatty amine to the binder-enveloped micro-particles.

3. In the Advisory Action, the Examiner contends that Brindle discloses a finishing powder, which is encapsulated in a binder. This is clearly incorrect.

4. The term "finishing powder" is well known in the art. The term refers to solid discrete particles that are not immobilized or enveloped in a binder. The term "finishing powder" is understood by those working in the condom industry to mean a loose powder (in which the particles are free to move) and not encapsulated, immobilized particles.

5. It is well known in the art that the purpose of a "finishing powder" is to serve as a dry lubricant to assist with processing of the article to which the finishing powder is applied. The powder is applied to prevent the condoms sticking together during manufacture and to allow them to unroll easily (see page 16 under 'General Requirements' and page 76 of WHO publication 'The Male Latex Condom: Specification and Guidelines for Condom Requirement 2003'. The complete document can be viewed at http://www.who.int/reproductive-health/publications/m_condom/index.html).

6. A solid particle that is dispersed in a binder cannot be considered a "finishing powder" because it is immobilized or enveloped in a binder.

7. In particular, the particles used in Brindle cannot be considered a "finishing powder" because the particles are encapsulated in a binder to form a film coating. The particles therefore are immobilized as part of a coating on the surface of the article. Once encapsulated and immobilized in this way, the particles would not be considered to be a "finishing powder" by those working in this field.

8. It is clear from the enclosed excerpt from the Family Health International (FHI) publication "The Latex Condom: Recent Advanced Future Directions" (available at www.fhi.org/en/rh/pubs/booksreports/latexcondom/index.htm) that "finishing powder" means a loose powder in which the particles are not encapsulated, and not immobilized.

9. In particular, in relation to processes for applying powders, such as "finishing powders" to condoms, it is stated that the process leaves a "dry powder on the condom to serve as a dry lubricant for further processing". (Chapter 4, side bar – lines 3 to 6 of paragraph 6). It is therefore clear that such powders consist of particles which are not encapsulated in any binder or coating.

10. The FHI publication also discusses "finishing powders" and dusting powders under the heading "Dry Powders" (see Chapter 5, page 5 of 8 in the attached print out). Since these powders are referred to as "dry powders" (the terms are used interchangeably), it is clear that they are applied to condoms as dry particulates, and not as particulates encapsulated in a binder (which would not be considered a "finishing powder"). There is a discussion of the potential problems of airborne exposure to the particles used in "finishing powders", for example corn starch (see 4th paragraph of the "dry powders" section). It is therefore clear that "finishing powders" can become airborne. Encapsulated particles cannot become airborne, so, as the skilled person understands, encapsulated powders cannot be considered "finishing powders".

11. In summary, the enclosed FHI publication clearly indicates that a "finishing powder" is understood to mean loose, non-immobilised powders, wherein the particles are not encapsulated in any binder, and are not present as a component of a film coating.

12. The WHO document referenced above ('The Male Latex Condom: Specification and Guidelines for Condom Procurement: 2003'), also evidences that the term "finishing powder" is understood to mean loose, non-immobilised powders, wherein the particles are not encapsulated in any binder. For example, on page 21 under "Design Requirements – Quantity of Lubricant Including Powder", it is stipulated that the quantity of lubricant, including powder, should be measured in accordance with the international condom standard ISO 4074:2002, Annex C. Annex C states that lubricant is removed from the condom by washing with a solvent, and that the 'lubricant' that is removed by washing has a greater mass than the amount of lubricant that was applied (see Annex C, section C.4). This is because the lubricant removed by washing includes the dressing, or finishing powder, which is also removed by washing, as stated in Annex C, C.4. This further supports the contention that the powder is not encapsulated in any binder or as part of a film coating, but is free to be removed from the condom surface by a simple washing technique (as the skilled person understands, if the particles were encapsulated, they could not be simply washed off the condom surface).

13. In addition, on the basis of the specification of the present patent application itself, the person skilled in this field would understand the term "finishing

powder" to exclude particles encapsulated in a binder, such as particles encapsulated in a film coating.

14. There is no indication in the present application, either implicit or explicit, that the particles of a "finishing powder" can be present encapsulated in a binder: binders are simply not used, and would not be used by those in this industry to make a finishing powder.

15. Furthermore, the present application discusses the potential for airborne exposure to "finishing powders" (paragraph [0003], final sentence). As the skilled person would understand, airborne exposure would not be possible if the particles were encapsulated in a binder. He would therefore understand that the particles of a "finishing powder" cannot be encapsulated in a binder.

16. Paragraph [0005] of the application discusses the problems of conventional "finishing powders", including the problem of standard magnesium carbonate "finishing powders" binding lubricant to form a stiff paste (paragraph [0005], third to last sentence). It would be apparent to the skilled person in the field that if the particles were present as part of a film coating (as in Brindle), then they would not be available to form a stiff paste with any lubricant. This further supports the contention that the skilled person would understand that the particles of the finishing powder are not encapsulated in a binder, and are not present as a component of a film coating.

17. Paragraph [0024] of the application relates to processes for applying "finishing powders" to a condom. The "finishing powder" is applied by washing the condom in an aqueous dispersion of the "finishing powder" and then dried. There is no mention in the application of the dispersion including any components which could function as a binder once the dispersion has dried. The skilled person working in the field would understand that the dispersion comprises particles of the "finishing powder" and that after drying, these particles will remain on the surface of the condom in a non-encapsulated, non-immobilized state. It would therefore be understood that the "finishing powders" of the present invention consist of solid discrete particles that are not immobilized or enveloped in a binder. This is the well-known meaning of the term in the art, as set out above.

Application No. 10/522,634
Declaration Under 37 C.F.R. §1.132

18. All statements made herein of my own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and may jeopardize the validity of the application or any patent issuing thereon.



Dr Adrian Łyszkowski

Date signed: 9th December 2008



Chapter 4: Recent Advances in the Research, Development and Manufacture of Latex Rubber Condoms



The Latex Condom: Recent Advances, Future Directions Chapter 4: Recent Advances in the Research, Development and Manufacture of Latex Rubber Condoms

The latex rubber condom produced today is more reliable than ever before, due primarily to improved quality management, but also to better formulations and packaging. It is also generally safer in terms of possible health problems, although some new concerns are arising regarding allergic or other toxic reactions to various components of latex condoms such as vulcanization accelerators, latex proteins, spermicides and finishing powders.

Latex Formulation

Latex condoms are made by mixing various chemicals with natural liquid latex, a process that affects the chemical and mechanical properties of the final product. Natural latex rubber deteriorates due to exposure to oxygen, ozone, heat, humidity, ultraviolet and visible light, mechanical fatigue or heavy metal contamination. Recent formulation improvements have focused on the chemical processes of oxidation and vulcanization and on the mechanical properties of stress and strain.

Oxidation is the deterioration of latex due to exposure to oxygen. To help prevent oxidation, most manufacturers now add antioxidants to the latex formulation, usually phenol compounds.

Vulcanization, a chemical curing process, increases the strength and resilience of rubber by forming sulfur-sulfur crosslinks between polymeric strands of the latex. Unvulcanized latex rubber is weak, loses its shape and can be sticky like chewing gum. Vulcanization enables elastomeric materials to return to their shape more easily after being stretched and reduces the amount of change in shape. The degree of vulcanization is controlled by the quantity and type of vulcanizate and temperature. Vulcanizing agents can act too fast or not fast enough, too thoroughly or not completely enough. If chemical agents added to the formulation work too long, excessive vulcanization in the package occurs, which can make condoms brittle, stiff and less elastic when opened and used.

In recent years, manufacturers have improved the control of the vulcanization process, using chemical activators and accelerators in a more reliable process. This has resulted in minimal or no in-package vulcanization.

Changes in the formulation affect the mechanical properties of stress and strain. A force

can be applied to compress or to stretch a material. With condoms, stress refers to the amount of force needed to extend the latex rubber a specified amount; stress is related to condom strength. Strain refers to how far latex rubber can be stretched and is related to elasticity. Both stress and strain contribute to the resistance of latex to breakage.

The relationship of stress and strain properties is called "modulus." Researchers working with condoms generally use the concept of "Young's modulus," which refers to a ratio of stress over strain (with stress as the numerator and strain as the denominator). Manufacturers, on the other hand, use the concept of "percent elongation modulus." This refers to the amount of stress per unit of cross-sectional area of the condom, measured in megapascals of pressure, at a given extent of strain through elongation, usually at 300 percent or 500 percent.

In either case, the term modulus refers to the stiffness or hardness of a material: a low-modulus material is more pliable and elastic, such as rubber bands, and a high-modulus material is stiffer but able to withstand a greater force, such as steel. This monograph uses the concept of "Young's modulus," since the studies discussed here use that concept.

Since latex condoms need to be both elastic and strong, the combination of the mechanical properties determines how reliably a condom performs. Manufacturers appear to be moving toward producing a more elastic condom. Findings from a series of FHI studies at six international sites compared a higher-modulus condom, called "extra-strong," with a lower-modulus, more elastic condom in human use. More than 3,000 of each type of condom were used. The more elastic condom broke less frequently (3.3 percent), compared to the "extra-strong" condom (4.3 percent), although the difference was not statistically significant. (Abeywickrema; Alvarado; Cordero; Figueroa; Ndumbu; Sidibe)

The mechanical properties of latex rubber condoms can change during aging if the latex film is not well formulated and protected from oxidation. Findings from a study conducted by PATH, with support from the FDA and FHI, found that stress and strain properties of latex condoms appear to deteriorate for different reasons, some oxygen-dependent and some oxygen-independent. Stress properties appear to be very susceptible to deterioration due to oxidation, while strain properties appear to be more sensitive to deterioration due to excessive vulcanization. The study compared changes in condoms artificially aged in the laboratory to those stored for various lengths of time and under various conditions in the United States and in four other countries. (Free)

Table 4-1. Stress, Strain and Modulus

<i>Term</i>	<i>Refers to</i>	<i>Indicator (Lab Test)</i>
Stress	Pressure or force	Tensile breaking strength (tensile) Breaking force (tensile) Air burst pressure (air burst)
Strain	Elasticity or extensibility	Percent elongation (tensile) Air burst volume (air burst)
Young's Modulus*	Ratio of stress to strain (stress is numerator; strain is denominator)	Tests listed above for stress and strain
Percent Elongation Modulus*	The amount of force or pressure applied to a material to extend that material to a percentage of its original elongation	Tensile breaking strength (tensile) Percent elongation (tensile)

* Higher modulus means higher proportion of stress properties, yielding stiffer condoms. Lower modulus means higher proportion of strain properties, yielding more elastic condoms. Two condom formulations can have the same degree of stress properties, but have different strain properties (or vice-versa) and thus have different

By evaluating the stress and strain properties of new and aged condoms from the same condom batch, laboratory tests can yield a "fingerprint," revealing one of three predominant causes of deterioration of the condom:

- **Oxidative Deterioration** -- A decrease in stress properties, with little or no decrease in strain properties, suggests oxygen-permeable or defective packaging (i.e., a hole in the package or an insufficiently sealed condom package) and a lack of antioxidant protection in the latex formulation.
- **Shelf Vulcanization** -- A decrease in strain properties, with little or no decrease in stress properties, suggests that the condoms were well protected from oxidative deterioration by good packaging but underwent shelf vulcanization, resulting in a stiffer, less elastic condom.
- **Localized Deterioration** -- A decrease in one indicator of stress properties (air burst pressure), with little or no decrease in the other two stress indicators (tensile strength and break force), suggests localized deterioration at the tip or parts of the condom unprotected by the condom roll. It also suggests high-temperature exposure and/or poor packaging. (Free)

Condom Packaging

Currently, most latex condoms are packaged in plastic cellophane, aluminum foil, or aluminum foil laminated with plastic cellophane. Some paper and paper laminates have been used worldwide, and may still be used in developing countries. The type of packaging affects the extent of condom deterioration during storage due to ultraviolet or visible light, oxygen, ozone, humidity, friction in the package and extreme temperatures.

For at least a decade, experts have known that translucent packages were generally not as protective as opaque packages. Research showed that condoms stored in translucent packages and exposed to ultraviolet (UV) light may deteriorate in only a matter of hours, while opaque packages protected condoms from UV exposure. (Anonymous 1987)

A recent study of package integrity conducted by PATH and supported by USAID and FHI showed convincingly that foil packaging offered the most protection from oxidative deterioration. The study found that plastic packaging is permeable to oxygen, while foil packaging is not. The study compared condoms stored for 36 to 48 months in a natural, tropical climate with those in a more temperate, climate-controlled setting. The condoms were tested yearly for strength, package integrity and oxygen content. Condoms from two U.S. manufacturers were used. (PATH)

The condoms packaged in only plastic cellophane deteriorated much faster than did those packaged in plastic-foil laminates. The decline in air burst pressure and volume from the air burst test were significantly higher for cellophane-packaged condoms, indicating the occurrence of oxidative deterioration in those condoms ($p < 0.0012$). This suggests that cellophane packaging is permeable to oxygen and thus may not prevent oxidative deterioration of condoms from occurring. A gas analysis of the two types of packaging found that oxygen content was consistently higher in the cellophane packages. (PATH)

A study focusing on the shelf life of condoms, conducted by PATH in conjunction with the FDA and FHI, found that condoms stored in impermeable, sealed foil packages have a shelf life beyond five years, even under tropical conditions. The study found that unpackaged condoms stored at high temperatures showed sharp decreases in air burst properties (both volume and pressure), rendering the condoms unfit for use within a three- to six-month period. (Free)

Currently, most studies by manufacturers of latex condoms that are naturally aged indicate that the shelf life of these condoms can be as long as five years, as long as they are not lubricated with spermicides. Spermicides have a shelf life of two to three years, however, thus shortening the shelf life of spermicidally-lubricated latex condoms.

Following a recent FDA ruling, condom manufacturers in the U.S. will be required to support their shelf life labels with laboratory test data. Beginning in March 1998, the labeling of latex condoms produced in the U.S. must contain an expiration date based upon the results of physical and mechanical testing performed after exposing naturally-aged and accelerated-aged condoms to varying conditions.

Latex Allergies

Research in recent years has raised concern about sensitivity and allergic reactions to latex condoms due to proteins in natural latex, to chemicals added to latex formulations, and to spermicides added to lubricants at the factory. Latex allergies are quite rare among the general population, however. Concerns about latex allergies should not inhibit sexually active people who are at risk of exposure to STDs from using condoms, since the risks associated with unprotected sexual contact are far greater than those from exposure to latex.

Some proteins found in natural rubber latex can cause sensitivity or allergic reactions. Condom manufacturers remove many of these natural proteins using a washing process called leaching. Leaching is done by dipping the condom in a series of baths, which usually contain hot water or a hot caustic solution. Leaching not only removes latex proteins, but may remove other components of latex as well.

The release of latex proteins can also result from interactions between the latex device and other chemicals, including the accelerators, antioxidants and dyes added to the latex formulation. (Rademaker; Turjanmaa) Accelerators, which increase latex cross-linking during vulcanization, can also cause allergic reactions.

Sensitivities or allergies usually develop gradually when mucosal and/or peritoneal surfaces come into repeated contact with protein allergens released from natural rubber latex. (Stratton; Deusch) The vagina and opening of the penis are both mucosal surfaces.

No studies have found that latex condoms result in high allergy rates. Among those allergies due to latex condom exposure, none has been extremely serious. Most allergic reactions to latex are minor, such as redness, itching, swollen and watering eyes, and swelling or inflammation, which subside when latex exposure is withdrawn. (Tomazic; Sussman) Persons allergic to latex should consider using synthetic condoms if they are available.

Experts are concerned that allergies to latex condoms may be increasing in prevalence and severity. Latex allergies are already a serious and growing problem among certain populations, due to the increased use of latex examination gloves and catheters.

In 1993, as a result of increased latex sensitivities and allergies among its patients, a hospital in Springfield, MA, USA, stopped using any latex medical products, using synthetic products instead. Recently, several manufacturers have received FDA clearance for "low-protein" surgical/examination gloves which are made by including additional and more complex leaching processes. In 1997, the FDA ordered makers of all medical devices that contain natural rubber latex, which include condoms, to warn that the products may cause allergic reactions. The order also covered packaging of the devices.

The presence of nonoxynol-9 (N-9) in the lubricant of condoms may increase the amount of protein released from the latex. A recent study found that protein levels from latex condoms with N-9 in their lubricants were approximately five times higher than the protein levels from condoms without N-9 in their lubricants. (Stratton) By increasing the amount of protein released from latex, N-9 may actually trigger a latex protein reaction.

Some condom users may be sensitive or allergic to N-9 itself. (Fisher; Doooms-Goosens) These users must be sure to use only condoms that are not lubricated with spermicides. In the U.S. about one-third of the condoms lubricated at the factory contain spermicides, usually in the form of N-9.

Dry Powders

Concerns have also emerged about the possible toxic effects of talc and other substances used in the finishing process of the condom. Dry dusting powders help keep the rolled up latex condom from sticking to itself. To accomplish this, manufacturers have used cornstarch, talc, mica, calcium carbonate, silicon dioxide, magnesium carbonate, lycopodium, dry silicone and other powders, with cornstarch currently the most commonly used. (Kang)

Talc, a natural mineral magnesium silicate, is a good dry lubricant. When used for cosmetic purposes, talc has not been a problem. (Wehner 1994, 1996) However, some experts think that when talc comes into contact with mucosal surfaces, it may be toxic. Because surgery usually involves contact with open or mucosal tissues and concerns were raised about the possible toxic effects of talc as a result of talc-coated surgical gloves, the use of talc on surgical gloves was stopped several years ago. (Kasper) When talc is used as a finishing powder on latex condoms, female partners of condom users may face a health risk due to the talc on the surface of latex condoms. The talc could migrate up the vagina, a mucosal surface, into the upper female reproductive tract, which may result in fallopian tube fibrosis with subsequent infertility. (Wehner 1996)

For many years, talc was the preferred dusting powder and was once commonly used in

latex condoms manufacturing. The relevance of using talc on condoms seems to fall somewhere between the realms of surgery and cosmetic use, but enough concern has emerged to cause a shift away from using talc in condom manufacturing. Currently, while condom manufacturers report that they do not use talc, (Anonymous 1995) some appear to have continued using it.

Cornstarch has become the new industry standard for finishing. While not as problematic as talc, it too could pose problems. Cornstarch is a heavily cross-linked carbohydrate with particle sizes ranging from 1 to 3 microns in diameter. A recent study found that, when used with surgical/examination gloves, cornstarch binds to allergenic latex proteins, and the more cornstarch used, the more protein binding occurs. (Tomazic) The latex-protein contaminated cornstarch particles are small enough to become airborne and can expose any persons in the vicinity to the latex proteins via the lungs, mouth, nose, eyes and skin. Direct contact with latex is not necessary to initiate a reaction.

Any wet lubricant applied to condoms before packaging should decrease the amount of airborne cornstarch. However, the cornstarch/latex protein complexes are more easily shed than latex proteins bound to the condom and could result in sensitivity or allergic reactions. Also, the airborne cornstarch/latex protein complexes remain an issue with unlubricated condoms.

Further research needs to be done to determine whether the dry powders currently used produce detrimental effects on users due to mucosal exposure. Researchers need to find new dry finishing powders, with one possibility being silicone powder. It has been widely used in other industries.

Conclusion

In recent years, better quality management, new research and the actions of manufacturers have led to a more reliable and safer latex condom.

Manufacturers now produce condoms that are more elastic with a chemical formulation that includes more antioxidants and better-controlled vulcanizates -- all steps that ensure condoms do not deteriorate as readily as in previous years. To better protect latex condoms from deterioration, manufacturers are using more impermeable, foil packaging; switching from plastic to foil or foil laminate packaging; and focusing more attention on tight package seals. These steps help preserve the integrity of the condoms, even under the most adverse storage conditions.

On the health front, manufacturers have moved away from using talc as a finishing powder, due to concerns about its possible toxicity. More research is needed on the safety of using cornstarch, the current preferred powder for finishing, or on determining a safer finishing powder. New research on allergies to latex proteins has also focused more attention on better leaching of proteins from the natural latex. Manufacturers are now able to produce condoms with less latex protein. More research is also needed to determine whether adding spermicides to the lubricant at the factory could result in more allergic reactions to latex.

by Caroline E. Gilmore

References

1. Abeywickrema D, Steiner M, Piedrahita C, et al. *Analysis of Actual Use Breakage Rates of Standard and Extra-strong Condoms: Sri Lanka*. Durham, NC: Family Health International, 1993.

2. Alvarado G, Piedrahita C, Holschneider S, et al. *Analysis of Actual Use Breakage Rates of Standard and Extra-strong Condoms: Mexico*. Durham, NC: Family Health International, 1991.
3. Anonymous. Monitoring condom quality. *Outlook* 1987;5(3):2-5.
4. Anonymous. Why is talc considered a problem substance? *Contracept Tech Update* 1995;16(11):136.
5. Cordero M, Piedrahita C, Holschneider S, et al. *Analysis of Actual Use Breakage Rates of Standard and Extra-strong Condoms: Dominican Republic*. Durham, NC: Family Health International, 1991.
6. Deusch E, Relder N, Martin C. Anaphylactic reaction to latex during cesarean delivery. *Obstet Gynecol* 1996;88(4) Part 2:727.
7. Dooms-Goossens A, Deveylder H, Gidi de Alm A, et al. Contact sensitivity to nonoxynols as a cause of intolerance to antiseptic preparations. *J Am Acad Dermatol* 1989;21:723-27.
8. Figueroa P, Martinez K, Joanis C, et al. *Analysis of Actual Use Breakage Rates of Standard and Extra-strong Condoms: Jamaica*. Durham, NC: Family Health International, 1992.
9. Fisher A. Condom dermatitis in either partner. *Cutis* 1987;39:281-85.
10. Free M, Srisamang V, Vail J, et al. Latex rubber condoms: predicting and extending shelf life. *Contraception* 1996;53:221-29.
11. Kang N, Griffin D and Ellis H. The pathological effects of glove and condoms dusting powders. *J Appl Toxicol* 1992;12(6):443-49.
12. Kasper C, Chandler P. Possible morbidity in women from talc on condoms. *JAMA* 1995;273(11):846-47.
13. Ndumbu F, Steiner M, Piedrahita C, et al. *Analysis of Actual Use Breakage Rates of Standard and Extra-strong Condoms: Kenya*. Durham, NC: Family Health International, 1991.
14. PATH. *Final Report - Package Integrity Study*. Seattle, WA: Program for Appropriate Technology in Health, 1996.
15. Rademaker M, Forsyth A. Allergic reaction to rubber condoms. *Genitourin Med* 1989;65:194-95.
16. Sidibe M, Steiner M, Joanis C, et al. *Analysis of Actual Use Breakage Rates of Standard and Extra-strong Condoms: Mali*. Durham, NC: Family Health International, 1991.
17. Stratton, P. Nonoxynol-9 lubricated latex condoms may increase release of natural rubber latex protein. Presentation at the International Conference on AIDS, Vancouver, BC, Canada. July 1996.
18. Sussman G, Beezhold D. Allergy to latex rubber. *Ann Intern Med* 1995;122:43-46.
19. Tomazic V, Shampaine E, Lamanna A, et al. Cornstarch powder on latex products is an allergen carrier. *J Allergy Clin Immunol* 1994;93:751-58.
20. Turjanmaa K, Reunala T. Condoms as a source of latex allergen and cause of contact urticaria. *Contact Dermatitis* 1989;20:360-64.
21. Wehner A. Letter to the editor. *Contracept Tech Update* 1996;17(3):32-33.
22. Wehner A, et al. Biological effects of cosmetic talc. *Food Chem Toxicol* 1994; 32:173-84.

[Return to table of contents](#)

Related Documents

Network Vol. 16, No. 3, Spring 1996: **Barrier Methods**

This page available at: <http://www.FHI.org/en/RH/Pubs/booksReports/latexcondom/recentadvances.htm>

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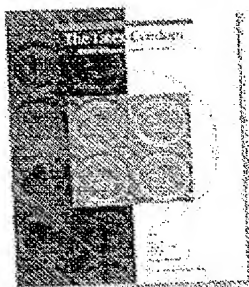
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- ▶ [Home](#)
- ▶ [Reproductive Health](#)
- ▶ [Publications](#)
- ▶ [Books and Reports](#)
- ▼ [The Latex Condom](#)
 - [Introduction: Why a Monograph on Latex Condoms?](#)
 - [Chapter 1: Pregnancy and STD Prevention](#)
 - [Chapter 2: Acceptability of condoms -- user behaviors and product attributes](#)
 - [Chapter 2 sidebar: Acceptability and Product Development](#)
 - [Chapter 3: User behaviors and characteristics related to condom failure](#)
 - [Chapter 3 sidebar: Using a Condom Correctly](#)
 - [Chapter 3 sidebar: Defining "Condom Failure"](#)
 - [Chapter 4: Recent Advances in the Research, Development and Manufacture of Latex Rubber Condoms](#)
 - [Chapter 4 sidebar: How a Latex Condom Is Made](#)
 - [Chapter 5: Standards, Specifications and Tests](#)
 - [Chapter 5 sidebar: Major Laboratory Tests for Condom Quality](#)

[Home](#) > [Reproductive Health](#) > [Publications](#) > [Books and Reports](#) > [The Latex Condom](#) > [Chapter 4 sidebar: How a Latex Condom Is Made](#)



Research

The Latex Condom: Recent Advances, Future Directions

Chapter 4 sidebar: How a Latex Condom Is Made

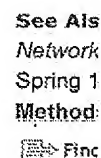
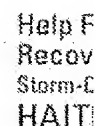
Latex comes primarily from the tropical rubber tree (*Hevea brasiliensis*), with the best quality found in Malaysia and Thailand. Latex is a natural elastomer and has the chemical name of cis-polyisoprene. Most other elastomers are synthetic. The liquid latex lies between the tree's bark and wood and is collected by making a series of slashes through the tree bark, which allows the latex to flow out of the tree. During collection, a small amount of ammonia is added to the raw latex to counteract the acid production of waste products from the bacteria that naturally feed on the latex and can cause the liquid latex to curdle. From this stage, latex is held in stainless steel tanks and processed with tools that are made only from stainless steel or other inert ingredients.

Liquid latex is actually a dispersion of rubber particles in water. Fresh raw latex consists of about 70 percent water and 30 percent rubber cells. The fresh latex is centrifuged, which concentrates it to approximately 60 percent solids. Concentrating latex reduces the cost of transport to the condom manufacturer and decreases the amount of time it takes to manufacture a condom. (Murphy)

The liquid latex is mixed with other chemicals to make a latex formulation for manufacturing. The latex formulation includes the liquid latex dispersion and various chemicals, including an antioxidant, a sulfur-based vulcanizing agent, and a vulcanizing accelerator. Accelerators are chemicals that increase both the rate and extent of cross-linking in the latex compound during vulcanization.

Latex condoms are produced by dipping plastic, ceramic, stainless-steel or glass mandrels mounted on a conveyor into a latex formulation.* The mandrel, most often glass, is dipped into the latex formulation in either a vertical or horizontal fashion, with virtually all manufacturers currently using a vertical dip. The mandrels go through a series of dips, rotating to spread the latex evenly. Between dips, each coat of latex is partially cured on the mandrel via hot-air drying in a carefully controlled tunnel-like oven on a conveyor system. Successive coats of latex are used to build the condom to the required thickness, with most manufacturers using two dips.

Brushes or water jets then roll up a section of the condom's open end to



- Chapter 5 sidebar: New Tests for Product Development
 - Chapter 6: Comparing Laboratory Tests With Human Use
 - Chapter 6 sidebar: Methodological Challenges In Studying Condoms
 - Chapter 7: The Development of Non-latex Condoms
 - Chapter 8: Conclusion -- What We Know and Research Priorities
 - Chapter 8 sidebar: Ten Reasons Why We Should Have Confidence in Condoms
 - Chapter 8 sidebar: Recommended Research Priorities
 - Acronyms and Abbreviations
- form the rim roll at the base of the condom, which stays in place because the rolled latex adheres to itself. Then, the condoms, still on mandrels, are dipped into one or more hot baths of either water or a caustic agent such as sodium hydroxide or potassium hydroxide. This removes some of the latex proteins from the condom, a process called leaching. Another round of curing is completed in a drying tunnel.
- The condoms are then removed from the mandrels using brushes or water jets, placed in an appliance similar to a clothes washing machine and washed with a powder slurry, usually cornstarch. After washing, the condoms are dried in a large appliance similar to a clothes dryer, which removes the liquid but leaves the dry powder on the condom to serve as a dry lubricant for further processing.
- Each condom is tested electronically for the presence of any holes. The condom is then rolled into its final configuration and placed between two layers of packaging material. If the condom is to be lubricated, a specified amount of lubricant and/or spermicide is put on the condom, and the two layers of packaging are then sealed.
- Most are lubricated with silicone or a water-based lubricant, which may or may not include a spermicide. The most commonly used spermicide is N-9, a water-soluble detergent (surfactant) that interacts with the cell membranes, killing sperm, bacteria and some viruses.
- Latex condoms are manufactured in different shapes, textures, colors, thicknesses, widths and lengths. A reservoir tip may or may not be included at the closed end of the condom. Some condom surfaces are smooth, while some are textured, sometimes in a design on the outside or inside surface. Most condoms are a dull opaque tan, although some are colored. Some condoms are manufactured with scent, flavoring (strawberry, mint and others), or other features.

Currently the two most common condom shapes are straight-sided and contoured/form-fitting. A straight-sided condom has basically the same diameter at its open and closed ends. A contoured condom is similar to a straight-sided condom, but with a slightly smaller width just below where the head of the penis would be. A third shape is tapered from the closed end to a smaller diameter at the open end, and a fourth has a bulbous tip at the closed end. The open-end diameter is about the same size for all shapes.

Condom dimensions vary. In terms of film thickness, almost all latex condoms are between 0.01 mm and 0.09 mm. Those made in the U.S. are generally from 0.03 mm to 0.07 mm (Hatcher) while those in Japan are generally 0.01 mm to 0.03 mm. (Concar) The lay-flat widths, corresponding to diameter, range from 47 mm to 55 mm, with most measuring 52 mm. Latex condom lengths range from 160 mm to 210 mm, with the majority measuring between 170 mm and 190 mm.

*Latex is a liquid, and the condom material is technically "latex rubber." In this monograph, as in common usage, we refer to the "latex" condom rather than the "latex rubber" condom.

by Caroline E. Gilmore

References

1. Concar D. Love me tender: making condoms that are both sensitive and safe is big business -- and getting bigger all the time. *New Scientist* 1993;140(1893):51-53.
2. Hatcher R, Trussell J, Stewart F, et al. *Contraceptive Technology*, 16th ed. New York: Irvington Publishers Inc., 1994.
3. Murphy JS. *The Condom Industry in the United States*. Jefferson, NC: McFarland and Co. Inc., 1990.

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